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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/101,825	07/17/98	GRUNHUJ LARSEN C	GRUNHUJ LARS

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HM22/1003

EXAMINER	
HAMUD, F	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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1- File Copy

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Office Action Summary

Application No.	Applicant(s)
09/101,825	Larsen et al
Examiner	**Art Unit**
Fozia Hamud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 11, 2001*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *18-41, 47, 49-53, 61, 63, and 65-79* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *18-41, 47, 49-53, 61, 63, and 65-79* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 15

18) ☒ Interview Summary (PTO-413) Paper No(s). 19

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. Applicant's amendment and arguments filed on 17 July 2001 in Paper NO:20 is acknowledged.

2. Claims 18 and 41 have been amended, claims 42-46, 48, 54, 55, 56, 58, 60, 62 and 64 have been canceled and new claims 73-79 have been added in the amendment filed on 11 July 2001 in Paper NO:20. Thus claims 18-41, 47, 49-53, 61, 63, 65-79 are pending and under consideration.

3. The following previous rejections and objections are withdrawn in light of Applicants amendments filed in Paper No.20, 07/11/01:

3a. Applicant's amendment limiting the peptides 6-20 amino acids in length overcomes the scope of enablement rejection drawn to the size of the peptides. Thus the rejection of claims 18-21, 24-41, 47, 65-79, based on 35 U.S.C. 112, first paragraph regarding the length of the peptides is withdrawn.

3b. The rejection of claims 49-52, 61 and 63, based on 35 U.S.C. 112, first paragraph regarding treating the recited diseases that are all mediated by IL-10 is reconsidered and withdrawn.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintenance of Scope of Enablement Rejection

Non-natural or unusual amino acids

4a. Claims 18-41, 47, and new claims 73-79 are rejected under 35 U.S.C. 112, first paragraph, as being enabling for claims directed to peptides having 6-20 amino acid residues and which comprise the following non-natural or unusual amino acids: norvaline, norleucine, N-methyl isoleucine,

alloleucine or any of the non-natural amino acids listed on page 18 of the instant specification, and methods of treating pancreatitis using said peptides. The specification is non-enabling for all peptides that are encompassed by the claims.

Applicants have amended claim 18 to limit the non-natural or unusual amino acid substitutions to the recited ones or to their D-isomers, however, instant specification is non enabling for a peptide which is 6-20 amino acids in length which comprises at least one of Xa, Xb, Xc, X4, X5 or X6 is a "all" possible non-natural amino acid. The only non-natural or unusual amino acid substitutions that are enabled by the instant specification are only those listed on page 18 of the specification. However, Applicants are non enabled for a peptide wherein X5 or X6 is "all" possible non-natural amino acids, because the skilled artisan can not predict that peptides comprising substitutions other than the non-natural amino acids listed in the speicificaiton would be active. Applicant's deceleration and exhibit showing the preparation and testing of synthetic peptide analogues of IT9302 provides support for enabling peptides with non-natural or unusual amino acid substitutions, wherein said non-natural amino acids are selected from the ones listed on page 18 of the instant specification. Applicant argues that several of the non-natural amino acids tested are not listed on pages 17-18 of the specification and that they can not accept limiting them to that list. Thus applicants submit reference to three catalogues that have already appeared on page 18, line 30 to page 19, line 2 of the specification. Applicants argue that this citation is a clear expression of an intent to rely on the disclosure of the referenced catalogues to supply "non-limiting examples" of non-natural amino acids.

This argument has been fully considered but is not deemed persuasive, because, since the material on the catalogues are essential material for providing enablement for the claimed peptide with "non-natural" amino acids substitution, this reference should have been incorporated by reference. "An application as filed must be complete in itself in order to comply with 35 U.S.C. 112, material nevertheless, may be incorporated by reference", (see, MPEP § 608.01(p). Thus, an application for a patent when filed may incorporate "essential material" by reference to a U.S. patent or a pending U.S. patent, (*Ex parte Shwarze).* However, Applicants can not incorporate the referenced catalogues, since they are neither U.S. patents nor pending U.S. patent applications.

4b. The rejection to claims 22-23 based on 35 U.S.C. 112, first paragraph, for not enabling a peptide amounting up to 30 amino acids is maintained for reasons of record on page 2 of the office action mailed on 30 January 2001.

4c. **Method of preventing or treating:**

The rejection to claims 49-52, 61 and 63 based on 35 U.S.C. 112, first paragraph for only enabling for a method of treating pancreatitis by using the peptides of SEQ ID Nos:1, 19-22 is maintained for reasons of record on page 7 of the office action mailed on 30 January 2001.

Applicants argue that the examiner gives too much weight to the number of diseases recited and too little weight that IL-10 is involved in all these diseases. Applicants also argue that they do not assert that "prevention" is absolute only that it occurs to a clinically beneficial degree.

These arguments are persuasive in part. The enablement issue regarding treating the listed diseases that are all mediated by IL-10 is reconsidered and withdrawn. However, preventing said

diseases is not enabled. The fact that Applicants show that pretreating rabbits with IT9302 prevents them from mortality, does not demonstrate that the disease is prevented. "Prevention" is described as a general term for the effort to prevent disease from occurring in unaffected individuals, as opposed to the treatment of individuals who are already affected; thus applicants have not demonstrated that the recited diseases are prevented to the point that unaffected individuals do not get them. Thus, a method of preventing a disease by a substance which has at least one of the properties listed in a-k of claim 49 is not enabled.

New Grounds of Rejections.

New matter rejection:

Claim rejections under 35 U.S.C. §112,

5a. Claims 18-41, 47and 73-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 18 recites " ....wherein X4 and X5 are independently selected from the group consisting of .. Methionine-S-oxide,.....L-Dab....." which language is new matter in the claims, since the instant specification does not disclose these specific non-natural amino acids. The specification fails to provide proper support. These non-natural amino acids have not been disclosed in the specification as originally filed, and applicants argue that they are listed on the catalogues which have been referenced. Applicants do not demonstrate that they were in possession of peptides that comprise

substitutions with Methionine-S-oxide or L-Dab. The issue with catalogues have been addressed in 4a of this office action. Thus the recitation of these non-natural amino acids introduce new matter into the claims, since they were never in the disclosure as originally filed.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday from 6:30AM to 4:00PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
26 September 2001

Gary L. Kunz
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